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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,046	03/26/2004	J. James Frost	16222Z (PC9584B)	9526
23389 7590 05/30/2007 SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 05/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/811,046	<b>Applicant(s)</b> FROST ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 3/26/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-11 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-11 is/are allowed.
- 6) ☒ Claim(s) 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 3/26/04 wherein the specification was amended; claims 1-5 and 12-14 were canceled; and claims 6 and 15 were amended.

Note: Claims 6-11 and 15-18 are pending.

## **APPLICANT'S INVENTION**

2. Applicant's invention is directed to method of diagnosing, estimating the severity of, and monitoring the progression of dementia in a subject by administering a compound of formulae I and II as set forth in independent claims 6 and 15.

## **112 SECOND PARAGRAPH REJECTIONS**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-18: The claims as written are ambiguous because in independent claim 15, the variable 'X' has not been defined. Thus, since claims 16-18 dependent on independent claim 15, those claims are also ambiguous. The claims were examined as if X = oxygen or sulfur.

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### 103 REJECTIONS

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musachio et al (Proceedings of the 43<sup>rd</sup> Annual Meeting, 1996, Vol. 37, No. 5, Supplement, Abstract No. 155, page 41P) in view of Maziere (Pharmac. Ther., 1995, Vol. 66, pages 83-101).

Musachio et al disclose a compound, CP-126,998, that is radiolabeled with carbon-11. The radiotracer is used for in vivo studies of acetylcholinesterase via PET analysis. In vivo mice studies indicated that the radiotracer had the greatest uptake in the striatum, a brain region, thirty minutes after injection. In addition, Musachio et al disclose that the study of acetylcholinesterase via PET analysis is of interest because of the reduced enzyme activity in Alzheimer's disease. Also, it is disclosed that initial results obtained by their studies indicated that [C-11] CP-126,998 might be useful as a marker for the study of acetylcholinesterase in humans using PET (see abstract). Musachio et al fail to specifically state that their invention may be used diagnosing, monitoring, or estimating the severity of dementia. However, the reference does disclose that acetylcholinesterase is a marker for Alzheimer's disease. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the compound disclosed in Musachio et al for dementia because the references

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analyzes the enzyme associated with Alzheimer's disease. Hence, a skilled practitioner in the art would recognize that one might analyze the enzyme and diagnose, monitor, or estimate the severity of Alzheimer's disease (a dementia condition). Furthermore, a skilled practitioner in the art would be motivated to use the method as set forth in the instant invention in a human because Musachio et al disclose that their initial studies indicated that the [C-11] CP-126,998 might be a useful marker for the study of acetylcholinesterase in humans via PET.

Musachio et al also fail to disclose other compounds wherein Applicant's R1 is various alkyl substituents. In addition, the reference fails to disclose other radioisotopes that may be conjugated to the compounds for PET or SPECT analysis.

Maziere discloses in vivo markers of acetylcholinesterase, vesicular acetylcholine transporter, brain and heart muscarinic receptors, or cholinergic nicotinic reporters. The markers may be used for single photon emission computerized tomography (SPECT) or positron emission tomography (PET). In particular, it is disclosed that for PET analysis carbon-11, fluorine-18, or bromine-76 may be used. In addition, Maziere discloses that iodine-123 may be used for SPECT analysis (see entire document, especially, page 83, abstract; page 85, section 2; page 94, section 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Musachio et al using the teachings of Maziere and generate compounds useful in Alzheimer disease and for detecting acetylcholinesterase in a subject's brain because (1) Maziere discloses that for PET studies the main positron emitter radionuclides for labeling are carbon-11, fluorine-18, and bromine-76. (2) Maziere discloses that for

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SPECT analysis iodine-123 is commonly used. (3) A skilled practitioner in the art would recognize that the replacement of a hydrogen atom with a lower alkyl, C1-C6 alkyl, is within the skill of a practitioner in the art because it is well established that the substitution of hydrogen for a lower alkyl on a known compound is not a patentable modification absent unexpected or unobvious results. (4) In addition, both Maziere and Musachio et al are directed to in vivo markers of acetylcholinesterase. Thus, the references may be considered to be within the same field of endeavors. Hence, their teachings are combinable.

#### **ALLOWABLE CLAIMS**


7. Claims 6-11 are allowable over the prior art of record. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a method of diagnosing, estimating the severity of, or monitoring the progression of dementia wherein a compound of formula I as set forth in independent claim 6 is administered.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones  
Primary Examiner  
Art Unit 1618

May 24, 2007